IN THE HIGH COURT OF JUDICATURE AT BOMBAY

CIVIL APPELLATE JURISDICTION

WRIT PETITION NO.4666 OF 1995

Shrikrishna Homeo Pharmacy
a Partnership firm, Registered under
the Indian Partnership Act, having
its office at 22, Budhwar Peth,
Pune 411 030. ..Petitioner.

Vs.

1. Union of India
Through Secretary, Ministry of
Health & Family Welfare (Dept.
of Health), Nirman Bhavan,
New Delhi.

2. The Joint Secretary
Govt. of India, Ministry of
Health & Family Welfare,
Nirman Bhavan,
Moulana Azad Road,
New Delhi.

3. The Drug Controller of India
Nirman Bhavan,

Moulana Azad Road,
New Delhi.

4. The Director,
Drug Technical Advisory Board,
Nirman Bhavan,
Maulana Azad Road,
New Delhi. ..Respondents.

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Mr.Nitin Apte and Ms.Anjali Joshi for the Petitioner.
Mr.A.S.Khan for Respondent Nos.1 to 4.

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CORAM : F.I.REBELLO &
DR.D.Y.CHANDRACHUD, JJ.
28th September, 2005.

ORAL JUDGMENT : (Per Dr.D.Y.CHANDRACHUD, J)

1. The Petitioner is a partnership firm registered under the Partnership Act, 1932, and carries on the business of manufacturing and selling homoeopathic medicines at a factory situated at Chinchwad. The homoeopathic medicines manufactured by the firm are broadly categorised

into:

i) Homoeopathic potential dilutions;

ii) Mother tinctures;

iii) Bio-Chemic Tablets;

iv) Specialities and tonics; and

v) Sundries including Globules, Diskets and ointments.

2. The challenge in these proceedings is to a notification issued by the Central Government on 22nd February, 1994 by which the provisions of Rule 106-B of the Drugs and Cosmetics Rules, 1945 were inserted in exercise of the rule making power under the Drugs and Cosmetics Act, 1940. Rule 106-B provides as follows :

> "**106-B. Prohibition of quality and percentage**
>
> No homoeopathic medicine containing more than 12% alcohol v/v (Ethyl Alcohol) shall be packed and sold in the packing or bottles of more than 30 millilitres, except that it may be sold to hospitals/ dispensaries in packings or bottles of not

more than 100 millilitres."

The prohibition in Rule 106-B is hence on the packing and selling of homoeopathic medicines with an alcohol content of more than 12% in containers of more than 30 millilitres. An exception has been made in the case of sale to hospitals and dispensaries where the dimensions of the container are not to exceed 100 millilitres.

3. On behalf of the Petitioner, it has been submitted that -

(i) Rule 106-B violates the fundamental rights of the Petitioner under Articles 14 and 19(1)(g) of the Constitution;

(ii) Rule 106-B makes an unreasonable discrimination between Homoeopathic and Ayurvedic manufacturers, since there is no such prohibition in the case of Ayurvedic medicines;

(iii) Rule 106-B is ultra vires the provisions of the Drugs and Cosmetics Act, 1940 and that the requisite procedure was not followed while enacting

the Rule;

(iv) The Drugs Technical Advisory Board was not competent to advice the Government in respect of Homoeopathic medicines since the Board did not have any representative with expert knowledge in the field of Homoeopathy.

4. An affidavit in reply has been filed in these proceedings by Deputy Drugs Controller (India), Central Drugs Standard Control Organization, West Zone, Mumbai, on behalf of the First, Second and Third Respondents. The attention of the Court has been drawn to the fact that similar writ petitions challenging the vires of Rule 106-B were dismissed by the Madras High Court on 16th December, 1995 and by the Patna High Court on 5th January, 1998. It has been stated that the prohibition in question was brought into effect with the object of placing a ban on large size packaging of Homoeopathic medicines containing more than 12% of alcohol. The prohibition, it has been stated, has been brought into effect in public interest in order to prevent the misuse of alcohol used in homoeopathic medicines and to provide

quality medicines to beneficiaries of the Homoeopathic system of medicine. It has been stated that the Rule was introduced pursuant to the recommendations of a Committee which enquired into the SURA tragedy that occurred in Delhi and that the findings of the Committee established that there was a rampant misuse of alcohol, for purposes other than medicinal preparations. Rule 106-B, it is urged, is a preventive measure against the misuse of alcohol which is made available to manufacturers at concessional rates for being used in the preparation of medicines. Very often such alcohol is found to be diverted for other purposes. Prior to the issuance of the notification by which Rule 106-B was brought into force, Homoeopathic medicines were available in the market in large packings of 450 millilitres and instances involving the wrongful use of alcohol used in the manufacture of these medicinal preparations were brought to light. Hence, it was proposed to ban or prohibit the packaging and sale of homoeopathic medicines in containers exceeding 30 millilitres. The Government of India is stated to have invited comments of manufacturers, retailers and traders of Homoeopathic medicines on the draft notification

which was widely circulated. The comments that were received were duly considered before the final notification was issued. The notification, it has been submitted, was issued by Government in the interests of consumers and of the society at large. The manufacture and sale of medicines, it is urged, can be controlled and regulated both with reference to the standards to be observed and the manner or method of packing.

5. The Drugs and Cosmetics Act, 1940 regulates the import, manufacture, distribution and sale of drugs and cosmetics. Section 5 of the Act provides for the constitution of a Drugs Technical Advisory Board to advise the Central and State Governments on technical matters arising out of the administration of the Act and to carry out the other functions assigned to it by the Act. The constitution of the Board is provided by sub-section (2) of Section 5, which is as follows :

"(2) The Board shall consist of the following members, namely, -

(i) the Director General of Health Services, *ex officio,* who shall be Chairman;

(ii) the Drugs Controller, India, *ex officio:*

(iii) the Director of the Central Drugs Laboratory, Calcutta, *ex officio;*

(iv) the Director of the Central Research Institute, Kasauli, *ex officio;*

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, *ex officio:*

(vi) the President of the Medical Council of India, *ex officio;*

(vii) the President of the Pharmacy Council of India, *ex officio;*

(viii) the Director of the Central Drug Research Institute, Lucknow, *ex officio;*

(ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government."

6. The Board is an expert body consisting of persons with wide experience in medicine, public health and pharmacy. Section 33 of the Act empowers the Central Government to frame rules after consultation with or on the recommendation of the Board for the purpose of giving effect to the provisions of Chapter IV which regulates the manufacture, sale and distribution of drugs and cosmetics.

7. The production, manufacture, distribution and sale of drugs has serious ramifications on public health as it does impinge upon the welfare of the community. The Drugs and Cosmetics Act 1940 and the Rules which have been framed thereunder, therefore, regulate the conditions under which the manufacture, sale and distribution of drugs can take place. In the affidavit in reply that has been filed in these proceedings, the circumstances

in which the provisions of Rule 106-B came to be inserted have been adverted to. The Central Government was seized of complaints relating to the misuse of alcohol used in medicinal preparations and more particularly those in relation to misuse of alcohol in the manufacture of Homoeopathic drugs. The imposition of a restriction on the size and packaging of the containers in which homoeopathic drugs incorporating more than 12% alcohol are sold is a reasonable restriction in the interest of the general public. The object of the restriction is clearly to prevent a misuse of the quantities of alcohol that are used in the manufacture of Homoeopathic preparations. There is hence absolutely no merit in the submission that the Rule is unconstitutional on the ground that there is a violation of the fundamental right under Article 19(1)(g) of the Constitution of India. The Madras High Court has repelled a similar challenge to the constitutional validity of Rule 106-B and on this ground that it violates Article 19(1)(g). In **Bhola Laboratories v. Union of India** in Writ Petitions 13679 and 26487 of 1995 decided on 6th December, 1995, Mr. Justice D. Raju (as the Learned Judge then was) held thus :

"The manufacture and sale of medicine can be regulated and controlled both with reference to the standards and the manner and method of packing and the wisdom or expediency of the requirement in this regard are not matters which should concern the Court unless it is demonstrated before this Court that grave injustice or prejudice is caused by such prescription and that any of the legally protected rights are violated. In this case, though it is claimed that it is easy and convenient both for the manufacturer and the dealer to pack it in the quantity of 450 ml. as has hither to been, as to how the said stipulation really affect the petitioner - manufacturer or the dealers or impedes his/their business is not demonstrated with any precision or clarity and that, therefore I do not see any legal grievance whatsoever substantiated in the submission made in this regard. As the rule stands, it appears even on a cursory

> reading that the object of the rule making authority is to prevent abuse of the drug concerned containing alcohol of more and above than a prescribed percentage for other than genuine and medicinal purposes by imposing a restriction in the manner of its package and that, in my view, no exception could be taken to the reasonableness of the measure. The plea based on Articles 14 and 19(1)(g) of the Constitution, therefore, fails and shall stand rejected."

The manufacture of drugs must be pursued in a manner which is consistent with the protection of public interest and Rule 106-B is intended to ensure that there is no diversion or misuse of alcohol which is used in the preparation of homoeopathic medicines.

8. There is absolutely no merit in the submission that there is a discrimination between manufacturers of Homoeopathic and Ayurvedic medicines. Even on the assumption that a similar

diversion of alcohol may conceivabley take place in the manufacture of Ayurvedic medicines, the argument of the Petitioner at the highest would be that the classification is under inclusive, but it is well settled that it is not necessary for the legislature to regulate every conceivable activity in order to regulate something. The legislature can recognize and distinguish between degrees of evil and regulate those areas where its intervention is most required. Such a classification cannot be regarded as arbitrary or unconstitutional.

9. The submission that Rule 106-B has been brought into force without complying with mandatory procedural requirements is based on the allegation that the Drugs Technical Advisory Board did not have any representative with an expert knowledge in the field of Homoeopathy. The constitution of the Board is provided for in Section 5(2) of the Act. Hence, it would not be for the Court to mandate any change in the statutory provision relating to the Constitution of the Board. That is for the Parliament to best determine. Moreover, in the affidavit in reply that has been filed in these

proceedings, it has been pointed out that as Homoeopathy is a full fledged and specialised branch of medicine, the Drugs Technical Advisory Board has constituted a sub-committee exclusively for homoeopathic science. Homoeopathic drugs fall within the meaning of the expression "drug" in Section 2(b) of the Act. Part VII A of the Drugs and Cosmetics Rules 1945 makes special provisions for the manufacture for sale or for distribution of homoeopathic medicines. Part IX A similarly embodies provision for the labelling and packing of Homoeopathic medicines. We are of the view that there is no merit in the submission that has been urged on behalf of the Petitioner. The Act has provided for a specific constitution of the Drugs Technical Advisory Board. The Board, it has been stated before the Court, duly considered the objections which were received from manufacturers before the Rules were brought into force.

10. In the circumstances, we find that there is no merit in the Petition. The Petition is accordingly dismissed.

(F.I.REBELLO, J.)

(DR.D.Y.CHANDRACHUD, J.)